UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK **(ECF)**

In Re RIVASTIGMINE PATENT LITIGATION (MDL No. 1661),	(05 MD 1661) (HB) (JCF) MEMORANDUM AND ORDER

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and Proterra AG (collectively "Novartis"), seek to amend their complaints in these consolidated patent cases to include claims for induced infringement under 35 U.S.C. § 271(e)(2). Defendants, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratory, Inc. (collectively "Reddy"), Watson Pharmaceuticals Inc. and Watson Laboratories, Inc. (collectively "Watson"), and Sun Pharmaceutical Ltd. ("Sun"), argue that plaintiffs' motion should be denied because the proposed amendments are futile. For the reasons set forth below, Novartis' motion is granted.

Background

A. The Regulatory Framework

Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-99 (the "FDCA"), a pharmaceutical manufacturer seeking to market a new drug must first obtain approval from the Food and Drug Administration (the "FDA") by submitting a new drug application

("NDA"). Purepac Pharmaceutical Co. v. Thompson, 354 F.3d 877, 879 (Fed. Cir. 2004); Allergan, Inc. v. Alcon Laboratories, Inc., 324 F.3d 1322, 1325 (Fed. Cir. 2003). If an NDA is approved, the FDA grants the manufacturer a five-year period of exclusive marketing for the drug. Allergan, 324 F.3d at 1325. The application must contain, among other things, the results of extensive testing, information regarding the drug's safety and effectiveness, and information about patents that cover the drug. 21 U.S.C. § 355(b)(1); Purepac, 354 F.3d at 879. The FDA publishes the patent information, which must be updated by the NDA owner, in a publication known generally as the "Orange Book." Allergan, 324 F.3d at 1325-26. "Method-of-use patents," that is, patents that cover a drug's specific uses, may be included in the Orange Book only if the covered uses have been approved by the FDA. Purepac, 354 F.3d at 880 (citing 21 C.F.R. § 314.53(b)).

With the goal of expediting access by generic drug manufacturers to the pharmaceutical market, Congress passed the "Hatch Waxman" amendments to the FDCA in 1984. See The Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35, and 42 of the United States Code); Purepac, 354 F.3d at 879. The amendments allow manufacturers seeking approval to market a generic version of an FDA-approved drug to file Abbreviated New Drug Applications ("ANDAs") which "piggyback on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." Id. Like NDA applicants, ANDA

applicants must address patents that cover, or ostensibly cover, the drug for which they are seeking approval. Id. One way in which they may do this is by submitting a statement that the patents which purport to cover the drug are "invalid or will not be infringed by the manufacture, use, or sale of the new drug" (a "paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon submitting a paragraph IV certification, an ANDA applicant must notify the patent holder, as well as the company that filed the NDA on which the ANDA "piggybacks." Purepac, 354 F.3d at 879. The patent holder then has 45 days in which to file a patent-infringement suit. Id.

B. The Infringed Patents

This case arises out of efforts by the defendants, Reddy, Watson, and Sun to market rivastigmine tartrate, which is sold by Novartis under the brand name Exelon. On April 21, 2000, the FDA approved Exelon for "the treatment of mild to moderate dementia of the Alzheimer's type". (Amended Complaint for Patent Infringement against Reddy ("Am. Compl."), attached as Exh. A to Declaration of Simon A. Fitzpatrick dated Jan. 12, 2004 ("Fitzpatrick Decl."), ¶ 26; Exelon Product Label, attached as Exh. 5 to Declaration of Lars P. R. Taavola dated Jan. 26, 2005 ("Taavola Decl."), at 9). Novartis subsequently submitted two patents purporting to cover Exelon for publication in the Orange Book, U.S. Patent Nos. 4,948,807 ("the '807 patent") and 5,602,176 ("the '176 patent"). (Taavola Decl., Exhs. 6 & 7). Each patent contains several claims, only two of which are at issue here: claim 4 of the '807 patent and

claim 5 of the '176 patent. (Plaintiffs' Memorandum in Support of their Motion to Amend the Complaints ("Pl. Memo.") at 3). Both claims address methods of using certain compounds to treat various medical conditions including Alzheimer's disease. (Pl. Memo. at 3; Taavola Decl., Exh. 6 at 14 & Exh. 7 at 4-5).

As stated in the complaints, the defendants here have filed ANDAs, which attempt to "piggyback" on the plaintiffs' NDA for Exelon. (Defendants' Joint Memorandum in Opposition to Plaintiffs' Motion to Amend the Complaints ("Def. Memo.") at 6). Reddy and Watson have submitted a paragraph IV certification stating that "the '807 and '176 patents are invalid, unenforceable or will not be infringed." (Am. Compl., ¶ 27; Answer and Counterclaim of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., attached as Exh. 3 to Taavola Decl., ¶ 27; Amended Complaint for Patent Infringement against Watson, attached as Exh. B to Fitzpatrick Decl., ¶ 27). Sun has submitted the same certification pertaining only to the '176 patent. (Amended Complaint for Patent Infringement against Sun, attached as Exh. C to Fitzpatrick Decl., ¶19).

Novartis subsequently filed a declaratory judgment action against Reddy, Watson, and Sun. The initial complaints against each defendant alleged infringement based only on the filing of the ANDAs "for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale" of rivastigmine tartrate capsules before the expiration of the '807 and/or '176 patents. (Am. Compl., ¶¶ 23-24). 35 U.S.C. § 271(e)(2) provides that:

> It shall be an act of infringement to submit–(A) an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under [Title 21 of the United States Code] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The plaintiffs are not the first parties to argue that this language creates a cause of action for infringement based solely on the filing of an ANDA. See Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1355 (Fed. Cir. 2003); Allergan, Inc. v. Alcon Laboratories, Inc., 200 F. Supp. 2d 1219, 1227 (C.D. Cal. 2002). Nevertheless, the Federal Circuit has soundly rejected this argument, holding that section 271(e)(2) merely creates "an act of infringement" for the purpose of forestalling the argument that no case or controversy yet exists. A plaintiff claiming induced infringement under section 271(e)(2) must still prove infringement under a traditional patent infringement analysis. Allergan, 324 F.3d at 1330-32; Warner-Lambert, 316 F.3d at 1365-66. Accordingly, Novartis now proposes to supplement its claims for induced infringement under section 271(e)(2) by adding the following paragraph:

> On information and belief, [defendant's] Rivastigmine Tartrate Products if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration constitutes direct infringement of the [relevant] patents. On information and belief, this will occur at [defendant's] active behest and with its intent, knowledge and encouragement. On information and belief, [defendant] will actively induce, encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiff's right under the [relevant] patents.

(Am. Compl., ¶ 26).

Discussion

A motion to amend is governed by Rule 15(a) of the Federal Rules of Civil Procedure, which states that leave to amend "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a); see Oneida Indian Nation of New York v. City of Sherrill, New York, 337 F.3d 139, 168 (2d Cir. 2003), rev'd on other grounds, ___ U.S. __, 125 S. Ct. 1478 (2005). Notwithstanding the liberality of the general rule, "it is within the sound discretion of the court whether to grant leave to amend," John Hancock Mutual Life Insurance Co. v. Amerford International Corp., 22 F.3d 458, 462 (2d Cir. 1994)(citation omitted), and for the proper reasons, a court may deny permission to amend in whole or in part. See Krumme v. Westpoint Stevens Inc., 143 F.3d 71, 88 (2d Cir. 1998).

Among the reasons for which a court may deny permission to amend is the "futility of amendment." Foman v. Davis, 371 U.S. 178, 182 (1962). A motion to amend may be denied as futile if the amendment could not withstand a motion to dismiss. See Milanese v. Rust-Oleum Corp., 244 F.3d 104, 110 (2d Cir. 2001); Smith v. CPC International, Inc., 104 F. Supp. 2d 272, 274 (S.D.N.Y. 2000).[1]

[1] Because only the futility of the amendment is at issue, I will not address the defendants' arguments to the extent they encompass assertions in the initial complaint. For example, the defendants contend that the plaintiffs' amendments should be denied because the plaintiffs have not pleaded that the use indicated in patents '807 and '176 is an FDA approved use. (Def. Memo. at 17-19). Since the plaintiffs' assertions regarding the uses indicated in the relevant patents and approved by the FDA are contained in the initial complaint, their sufficiency is not

Although the law of the Federal Circuit governs questions of patent law, the law of the regional circuit applies to procedural questions that are not specific to patent law. See Madey v. Duke University, 307 F.3d 1351, 1358 (Fed. Cir. 2002). Thus, Second Circuit law governs the legal standards for pleading under Rule 8(a) of the Federal Rules of Civil Procedure and for dismissal under Rules 12(b)(1) and 12(b)(6).

The defendants argue that Novartis' proposed amendments are futile because they are speculative and because they fail to set out the "specific intent" and affirmative conduct required to state a claim for induced infringement under 21 U.S.C. § 271(e)(2). (Def. Memo. at 20-21). I will address each of these contentions in turn.

First, it is not fatal to the plaintiffs' motion that the proposed amendments pertain to "what [the] defendants may do in the future." (Def. Memo. at 20). "A claim under 35 U.S.C. § 271(e)(2) is, by its very nature, speculative to a certain degree[.]" Allergan, 324 F.3d at 1331. Indeed, in comparing actions brought under section 271(e)(2) and traditional infringement claims brought under section 271(a), the Federal Circuit has stated that "the only difference . . . is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997). Thus,

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at issue here. (Complaint for Patent Infringement against Reddy, ¶¶ 16, 19, 22).

"[w]hile a section 271(e)(2) induced infringement claim may be speculative, it is not sufficiently so to contravene the case or controversy requirement." Allergan, 324 F.3d at 1331-32.

Second, contrary to the defendants' assertions, the proposed amendments adequately set out the intent and conduct required to state a claim for induced infringement under 35 U.S.C. § 271(e)(2). As noted above, in order to succeed on an induced infringement claim under section 271(e)(2), a plaintiff must prove infringement under a traditional patent infringement analysis. Such an analysis requires proof that "if the ANDA is approved, the accused infringer will induce a third party to directly infringe the asserted patent and that the accused infringer knows or should know that his actions will induce infringement." Allergan, 324 F.3d at 1336 (citing Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 553 (Fed. Cir. 1990)). The amendments proposed here address each of these elements; the plaintiffs allege that third parties will directly infringe the '807 and '176 patents at the "active behest" and with the intent of defendants. The defendants assert that the plaintiffs must establish "specific intent" and allege "affirmative conduct" such as funding clinical studies or employing a sales force. (Def. Memo. at 12). However, "specific intent" in the induced infringement context requires that a defendant intend specifically to encourage another's infringement, as opposed to merely knowing "of the acts alleged to constitute inducement." Manville Sales, 917 F.2d at 553. And, under the notice pleading standard provided in Rule 8 of the Federal Rules of Civil

Procedures, the plaintiffs are not, at this stage in the litigation, required to plead with particularity specific acts of inducement or encouragement of third parties. See Takeda Chemical Industries, Ltd. v. Watson Pharmaceuticals, Inc., 329 F. Supp. 2d 394, 401 (S.D.N.Y. 2004) (holding that plaintiff stated traditional claim for induced infringement where it alleged existence of patent and claimed that defendant "[had] taken and [would] take acts to induce infringement of those patents"). Thus, the proposed amendments are not barred on the grounds of futility.

Conclusion

For the reasons set forth above, Novartis' motion to amend is granted.

SO ORDERED.

James C. Francis IV

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UNITED STATES MAGISTRATE JUDGE

Dated: New York, New York
April 25, 2005

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